

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,545	09/14/2001	Detlef Palm	512100-2021	7110

20999 7590 05/20/2003

FROMMER LAWRENCE & HAUG  
745 FIFTH AVENUE- 10TH FL.  
NEW YORK, NY 10151

EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 05/20/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/936,545

Applicant(s)

PALM ET AL.

Examiner

Simon J. Oh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 29-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1615

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's amendment and request for extension of time, both received on 19 February 2003.

### ***Claim Objections***

The objection to Claim 22 is rendered moot with the cancellation of that claim.

### ***Claim Rejections - 35 USC § 101 and 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claim 24 under 35 U.S.C. 112, second paragraph is rendered moot with the cancellation of that claim.

The rejection of Claims 25-27 under 35 U.S.C. 101 and 112 is rendered moot with the cancellation of those claims.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1615

The rejection of Claims 19-27 under 35 U.S.C. 102(b) is rendered moot with the cancellation of those claims.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 19-27 under 35 U.S.C. 103(a) is rendered moot with the cancellation of those claims.

Claims 29-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raffegeau in view of Casper (U.S. Patent No. 5,422,119).

The Raffegeau patent teaches a packaging for individually packaged products in bags (See Page 1, Lines 1-3). This product has a casing of cardboard or plastic in the shape of an inverted "U", in which the individually packaged bags are inserted and stapled or glued. A wedge in the upper portion of the packaging allows for the thickness of the products contained in the bags and the bags themselves to be compensated (See Page 1, Lines 19-24). An illustration is given where more than one wedge is included in the packaging (See Figure 3). The casing of the packaging comprises closure that further comprises a tongue that can be adjusted and inserted into a slot (See Page 1, Lines 25-31; Page 2, Lines 25-27; and Figure 5). The individual bags in the packaging may be perforated along a dotted line (See Page 1, Lines 39-41; and Figure 2). It is the position of the examiner that the illustration of the edges of the individual bags in Figure 1 is sufficient for anticipation of the applicant's claim limitations drawn to superposed sections of

Art Unit: 1615

the edges of adjacent bags that are offset in parallel. As such, the figure is considered to be an enabling disclosure (See Figure 1; and MPEP § 2125). This packaging is deemed particularly suitable for use with hygiene products and pharmaceuticals (See Abstract, translation not provided). Furthermore, the inner and outer surfaces of the outer packaging are suitable for instructions, dosage information, and contra-indications printed thereon (See Page 1, Lines 32-35).

The Raffegeau patent does not explicitly disclose that the disclosed packaging can be used in combination with transdermal hormone therapy.

The Casper patent teaches methods of hormone replacement therapy and packages of pharmaceutical transdermal patches used to implement such methods. The package provides patches arranged in phases, each phase consisting of a transdermal estrogen substance alone, or a transdermal estrogen substance in combination with a transdermal progestin substance (See Abstract; and Column 5, Lines 27-48). It is further disclosed that the sequence of administration of the transdermal patches and their arrangement in a predetermined order is critical to the success of the invention (See Column 8, Lines 13-21). The patches may be also individually sealed in a protective pouch (See Column 9, Lines 16-20). See also Claims 20-38.

It would be obvious to one of ordinary skill in the art to combine the disclosures of Raffegeau and Casper into the objects of the instantly claimed invention. The disclosure in Casper describes the disclosed packaging in broad terms, only citing certain features that the packaging should possess in order to carry out the best mode of the disclosed method of treatment, such as the arrangement of transdermal patches in sequential phases, and that the patches may be individually sealed within a protective pouch. It is therefore the position of the

Art Unit: 1615

examiner that the specific physical structure of the packaging itself is not critical so long as it allows for the organization of the patches in phases within pouches as described in Casper, and that one of ordinary skill in the art would be motivated to combine the disclosure of Casper with any prior art reference, including Raffegau, that fits this general criteria, with a reasonable expectation of success of producing a packaging that will facilitate the administration of transdermal patches as disclosed in Casper. Given the arrangement of the bags in the packaging disclosed in Raffegau, it is the position of the examiner that their removal from the packaging is both inherent and obvious. The Raffegau patent describes all of the physical components of the instantly claimed invention, as well as giving enabling disclosures regarding features of the instantly claimed invention, including the particular arrangement of the individual bags within the disclosed packaging. Claim 38 contains two limitations, "used in the first phase of hormone replacement therapy", and "used in the second phase of hormone replacement therapy". The examiner considers these limitations to be drawn to a future intended use of the claimed invention, and as such, they are not given patentable weight. The instantly claimed invention is *prima facie* obvious.

### ***Response to Arguments***

Applicant's arguments filed 19 February 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that a predetermined sequence of removal of bags from a packaging system is not disclosed by the prior art, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the

Art Unit: 1615

prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). This holds true both for the previously rejected claims, as well as the present claims in the instant application.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Art Unit: 1615

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sj  
May 16, 2003

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600